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EXAMINER

JOHNSON III, HENRY M

ART UNIT PAPER NUMBER

3739

DATE MAILED: 01/27/2004

24

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/756,130

Applicant(s)

HARTH ET AL.

Examiner

Henry M Johnson, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 107-229 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 107-229 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☒ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION*****Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 107-111, 116-120, 122, 123, 127-132, 134-138, 143-147, 149-154 and 156-161 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 10/098592. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are an obvious change of scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Objections***

Claims 139-144 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 112-117 respectively. Claim 161 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 151. Claim 196 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 192. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 107-149, 159, 182, 193, 194, 213 and 214 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 107 recites the limitation "the patient" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 127 and 182 are indefinite as they cite an area not related to the device. It would be proper to claim the spot size as it is directed related to the device.

Claims 137 and 159 are indefinite in that it is not clear if multiple sources are used for producing the multiple wavelengths or sophisticated optics.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 107, 111, 113-115, 117-121, 124, 125, 128, 131-133, 137, 138, 140-142, 144, 150-153, 155, 160, 161, 163, 164, 165, 167-169, 171-176, 179, 180, 183, 184, 189 and 190 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,620,478 to Eckhouse. Eckhouse discloses an apparatus for therapeutic electromagnetic treatment that provides light at wavelengths from 300 to 1000 nanometers, the exact spectrum being selected by optical filters (optical system) as desired with narrow bandwidths (Col. 5, lines 45-55). The removal of ultraviolet wavelengths is specifically cited. Energy densities of up to 20 J/cm<sup>2</sup> are cited although it is implicit that higher levels can be achieved using exposure times. Eckhouse discloses control using a microprocessor to provide timing functions and trigger signals that

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includes a screen (display) and keyboard (Col. 16, lines 14-22). A handle (Fig.2, #13) is interpreted as a mechanical fixture for positioning the device. The citing of a "plurality of discontinuous applications" and "sufficient to effectively treat a skin disorder" do not impart additional structure to the device and are therefore given no patentable weight.

Regarding claims 113, 114, 141, 163, 166 and 167, the device is capable of delivering a dose of  $36 \text{ J/cm}^2$  as this is a function of time. Further, it is cited that  $9 \text{ J/cm}^2$  is sufficient to effectively treat the disorder making it unclear why additional dosage would be necessary.

Regarding claims 117, 144 and 171, the claims add no further structural limitation and are rejected with the base claim.

Regarding claim 118, 152, 155 and 172, Eckhouse teaches a control system that includes timing and triggers associated with pulse duration.

Regarding claims 119, 120, 153 and 173-175, being a handheld unit, the device may be spaced as desired by the operator.

Regarding claims 121 and 176, the optics provide the means for delivery.

Regarding claims 124, 125, 179 and 180, the treatment times relate to the method of treatment. However, with the control features disclosed, it is implicit that the time is programmable to any treatment time.

Regarding claims 128, 131, 132, 183 and 184, Eckhouse teaches an elliptical reflector for directing the output into an optical fiber (Col. 9, lines 28-38).

Regarding claims 137, 159 and 189, the choice of spectral filters defines the output illumination.

Regarding claims 138, 160 and 190, the intended use does not impact the device structure.

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Claims 191, 193-195, 197-201 and 210 are rejected under 35 U.S.C. 102(b) as being anticipated by Sigurdsson V, et al., "Pharmacology and Treatment. Phototherapy of Acne Vulgaris with Visible Light", *Dermatology*, Vol 194, no. 3, 1997, pages 256-260 (hereinafter referred to as Sigurdsson). Sigurdsson discloses the treatment of acne vulgaris using several discrete wavelengths of visible light including, specifically, violet light with a spectral distribution of 400 to 450 nm (Fig. 2) that is delivered in a treatment regimen of three times weekly (plurality of discontinuous applications) for a total of 20 sessions with dosage of 20J/cm<sup>2</sup> per session. The violet light has substantially no UV radiation and Sigurdsson's tests indicated that UV was not necessary for a therapeutic effect and is discouraged due to the possibility of negative effects (page 259, Col. 2, lines 5-8). The results showed a reduced level of porphyrins in the acne lesions and suggest this causes photodynamic destruction of the acne. The skin temperature during treatment was kept below 41°C (Page 257, Col. 1, paragraph 9).

Regarding claims 193 and 194, the production of peroxides is interpreted as due to the reaction as stated in the claim although Sigurdsson makes no specific reference to reaction with oxygen to produce peroxides, this result is implicit in that the radiation doses and times are the same.

Regarding claim 198, Sigurdsson discloses the use of a filter to remove UV from the violet light (page 257, Col. 1, paragraph 5).

Regarding claims 200 and 201, the treatment time is disclosed as 20 minutes per session.

Claim 202 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sigurdsson. Sigurdsson discloses the treatment of acne on the face, back or chest, however does not disclose a quantitative area. Adult males would obviously have back or chest areas exceeding 200 cm<sup>2</sup>.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 108-110, 129, 130, 136, 145-147, 158 and 188 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,620,478 to Eckhouse.

Regarding claim 108, Eckhouse discloses the claimed invention except for multiple illumination sources. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use multiple illumination sources to treat an area since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claim 109, it is well known in the art and it would have been an obvious matter of design choice to utilize any of a number of light sources including an ion krypton gas laser in the device of Eckhouse since Applicant has not disclosed that a particular light source provides an advantage, is used for a unique purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with an metal discharge lamp, diode laser, LED or an ion krypton gas laser because all provide a means to deliver the spectrum desired.

Regarding claim 110, it is well known in the art and it would have been an obvious matter of design choice to use various optics in the device of Eckhouse to shape and deliver the treatment light since Applicant has not disclosed that two orthogonal cylindrical lenses provides an advantage, is used for a unique purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with

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cylindrical lenses, concave lenses or convex lenses because all provide a means to shape and focus the beam as desired.

Regarding claims 129, 130, 136, 158 and 188 it is well known in the art and it would have been an obvious matter of design choice to utilize any of a number of light sources including a gas discharge lamp in the device of Eckhouse since Applicant has not disclosed that a particular light source provides an advantage, is used for a unique purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with an metal discharge lamp, diode laser, LED or an ion krypton gas laser because all provide a means to deliver the spectrum desired.

Regarding claims 145-148, Eckhouse teaches a mechanical fixture (handle) that makes the unit capable of adjustment and further includes optics for delivery of the treatment beam.

Claims 112, 139, 162 and 166 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,620,478 to Eckhouse in view of U.S. Patent 6,273,884 to Altshuler. Eckhouse is discussed above, but does not teach cooling of the treated area. Altshuler discloses cooling for a photo cosmetic device that cools treated skin areas and the radiation sources (abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the cooling system as taught by Altshuler in the invention of Eckhouse to maintain the treated skin at an acceptable temperature.

Claims 116, 122, 123, 126, 143, 149, 154, 170, 177, 178 and 181 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,620,478 to Eckhouse in view of U.S. Patent 5,843,143 to Whitehurst. Eckhouse is discussed above, but does not disclose power densities. Whitehurst teaches intensities of up to  $9\text{W}/\text{cm}^2$  focused into a fiber optic (Col. 3, line 51). Since an optical fiber collimates the beam, it is inherent that the intensity would remain above  $40\text{ mW}/\text{cm}^2$  at a distance of 30cm. It would have been obvious to one having ordinary



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skill in the art at the time the invention was made to use power densities as taught by Whitehurst in the invention of Eckhouse to insure efficient treatment.

Claims 127 and 182 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,620,478 to Eckhouse in view of Sigurdsson. Both are discussed above, but Eckhouse does not teach a treatment area. Sigurdsson discloses the treatment of acne on the face, back or chest, however does not disclose a quantitative area. Adult males would obviously have back or chest areas exceeding 200 cm<sup>2</sup>. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the treatment parameters (i.e. dosages on a back) as taught by Sigurdsson in the invention of Eckhouse to provide the treatment radiation of the prescribed parameters.

Claims 134, 135, 156, 157, 186 and 187 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,620,478 to Eckhouse in view of U.S. Patent 4,930,504 to Diamantopoulos. Eckhouse is discussed above, but does not teach the use of diodes and LEDs. Diamantopoulos discloses a device for treating tissue using an array of semiconductors that may be diodes or LEDs (Col. 5, lines 50-55) and may be in the visible spectrum (Col. 5, line 21). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use LEDs as taught by Diamantopoulos in the invention of Eckhouse to achieve the desired treatment wavelengths using less expensive alternative light sources.

Claim 185 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,620,478 to Eckhouse as applied to claim 164 above and further in view of U.S. Patent 6,165,170 to Wynne et al. Eckhouse is both discussed above, but does not teach display of the treated area. Wynne teaches a laser system for treating skin that uses a display with a touch screen (Col. 11, lines 38-55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the integrated display as taught by Wynne in the

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device of Eckhouse to guide the procedure and maintain records of the treatment process in the computer.

Claims 192, 196, 211-222 and 228 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sigurdsson V, et al., "Pharmacology and Treatment. Phototherapy of Acne Vulgaris with Visible Light", Dermatology, Vol 194, no. 3, 1997, pages 256-260. Sigurdsson is discussed above, and teaches treatments of 20 minutes each, producing a dose of 20 J/cm<sup>2</sup> (violet). The intensity is derived as 16.6 mW/cm<sup>2</sup> (Joules = Watts X Seconds). It is disclosed by the applicant that "9 J/cm<sup>2</sup> is sufficient to effectively treat the skin disorder", therefore, it would have been an obvious matter of design choice to increase the intensity in the method of Sigurdsson since Applicant has not disclosed that increased intensities provide an advantage, are used for a unique purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any intensity above the level sufficient to effectively treat the skin disorder.

Claims 203, 223 and 229 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sigurdsson as applied to claims 191 and 211 above, and further in view of U.S. Patent 5,620,478 to Eckhouse. Sigurdsson and Eckhouse are both discussed above. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the integrated controls as taught by Eckhouse in the methods of Sigurdsson as such controls are well known in the art for tighter controls over the process to reduce the possibilities of human error.

Claims 204 and 205 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sigurdsson, in view of U.S. Patent 5,620,478 to Eckhouse as applied to claim 203 above and further in view of U.S. Patent 6,165,170 to Wynne et al. Sigurdsson and Eckhouse are both discussed above, but do not teach display of the treated area. Wynne teaches a display with a

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touch screen as discussed above. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the integrated display as taught by Wynne in the methods of Sigurdsson/Eckhouse to guide the procedure and maintain records of the treatment process in the computer.

Claims 206-208 and 224-226 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sigurdsson V, et al., "Pharmacology and Treatment. Phototherapy of Acne Vulgaris with Visible Light", Dermatology, Vol 194, no. 3, 1997, pages 256-260. Sigurdsson is discussed above, but does not specifically teach light sources. It is well known in the art and it would have been an obvious matter of design choice to choose any number of different illumination means to achieve the treatment wavelengths methods of Sigurdsson since Applicant has not disclosed that a specific source provides any advantage, is used for a unique purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a gas discharge lamp, diode laser, LED or combination of sources because all provide a means to deliver the spectrum required for treatment.

Claims 209 and 227 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sigurdsson V, et al., "Pharmacology and Treatment. Phototherapy of Acne Vulgaris with Visible Light", Dermatology, Vol 194, no. 3, 1997, pages 256-260 in view of U.S. Patent 5,259,380 to Mendes et al. Sigurdsson is discussed above, but does not teach the use of red light in the treatment. Mendes discloses the use of red LEDs for the treatment of skin disorders (Col. 8, lines 29-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the red wavelengths as taught by Mendes in the invention of Sigurdsson to complement the violet and green light to treat a skin disorder as it is well known the longer wavelengths penetrate deeper into tissue providing treatment to these deeper tissue levels.

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***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 4,790,500 to Mori teaches a mechanical fixture for supporting a radiation delivery device for medical treatment.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M Johnson, III whose telephone number is (703) 305-0910. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Henry M Johnson, III  
Patent Examiner  
Art Unit 3739

Hmj

  
Lee Cohen,  
Primary Examiner